DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M3837A

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-58

June 8, 2000

Jesus Rodriquez, President
Cosmetic Corporation of America
9750 N.W. 91 Court
Medley, Florida 33178

Dear Mr. Rodriquez:

FDA Investigator, Jennifer Donzanti, inspected your manufacturing facility located in Medley, Florida on April 26 & 27, 2000 and determined that you manufacture sunscreen products under contract for [redacted]. Sunscreen products are drugs as defined by section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) and, because they are labeled to provide minimal to total protection from the sun's harmful rays.

The sunscreen products that you manufacture are adulterated within the meaning of section 501(a)(2)(B) of the Act because the methods used in, or the facilities or controls used for, their manufacture do not conform to the current good manufacturing practice (CGMP) regulations for drugs specified in Title 21, Code of Federal Regulations (CFR), Part 211.

The inspection revealed that there is no assurance that your sunscreen products meet applicable standards of identity, strength, quality and purity because you failed to comply with CGMPs as follows:

1. You failed to conduct finished product testing for the identity and strength of each active ingredient as required by 21 CFR 211.165. For example, product identified as SBS SPF 50 Lotion, was shipped prior to receipt of the test results (FDA 483, Item #1), no finished product testing of the active ingredient (Zinc Oxide) was performed for "All Terrain SPF 15 Repellant" prior to release for distribution (FDA 483, Item #3), no waterproof ingredient testing was conducted for products labeled "waterproof" (FDA 483, Item #5), and no testing was conducted to determine the SPF rating for those sunscreen products declaring a specific SPF rating on the label (FDA 483, Item #6).

2. You failed to sign finished product test results, identify the method of analysis and the person who conducted the analysis as required by 21 CFR 211.194(a). For example, the identity of the analytical lab, the person conducting the analysis, and what methods were used to conduct finished product testing were not documented (FDA 483, Item #2).

3. You failed to collect and maintain reserve samples for each lot of incoming active ingredients and finished products manufactured as required by 21 CFR 211. 170. For example, no samples are maintained for any incoming raw material, active ingredients (FDA 483, Item #9), or of any finished sunscreen drug products manufactured (FDA 483, Item #11).

4. You failed to validate the cleaning processes for equipment used to manufacture sunscreen products to prevent malfunctions or contamination of drug products as required by 21 CFR 211.167. For example, no documentation was available that shows the current cleaning procedure is appropriate and effective (FDA 483, Item #10.

5. You have failed to establish, maintain and implement written procedures covering recalls (21 CFR 211.150(b)), consumer complaints (21 CFR 211.198(a), and calibration/maintenance of equipment (21 CFR 211. 67 and 68). For example, there are no written procedures covering these operations setting forth the schedule and established requirements to be met (FDA 483, Item #13 & 15).

6. You failed to include product labels and documentation of sampling of active ingredients and finished products in the respective batch production records as required by 21 CFR 211.180(a) & (b).

7. You failed to label your sunscreen products with expiration dates as required by 21 CFR 211.137. For example, no testing has been conducted to assure your products meet applicable standards of identity, strength, quality and purity evidenced by an expiration date supported by appropriate stability testing (FA 483, Item #4).

8. You failed to implement and maintain a written stability testing program used to determine appropriate storage conditions and expiration dates as required by 21 CFR 211.166. For example, the one month accelerated stability test you conducted without active ingredient testing was not repeated and does not support any meaningful expiration date (FDA 483, Item #4).

It is your responsibility as a drug manufacturer to assure that all requirements of the GMP regulations are met. You are also responsible for ensuring that all of the drug products you manufacture are safe and effective for all of their labeled claims.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

We request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the GMP regulations so that a verification inspection can be scheduled. Once your corrective actions have been verified, we can withdraw our advisory to Federal agencies concerning the award of government contracts, and will allow FDA to review any pending applications.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps that you have taken to correct these violations and to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Tim Couzins, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida, 32751, telephone (407) 475-4728.

Sincerely,

Edward R. Atkins

Edward R. Atkins
Acting Director
Florida District

cc: Stephen Dawes, owner
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